IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, NORTH CAROLINA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN, *ex rel.* CATHLEEN FORNEY,	:	CIVIL ACTION NO. 15-6264
Plaintiffs/Relator,	:	
v.	:	
MEDTRONIC, INC.,	:	
Defendant.	:	

MEMORANDUM OPINION

Smith, J. June 19, 2017

The False Claims Act ("FCA"), 31 U.S.C. § 3729, prohibits causing the submission of false claims for payment to federal healthcare programs, and thus prohibits providing kickbacks to healthcare providers knowing that those providers will subsequently submit claims to the government. The relator filed this *qui tam* action pursuant to the federal FCA and twenty-nine state-law false claims statutes, alleging that the defendant paid healthcare providers illegal kickbacks in the form of free services and staff to induce providers to choose the defendant's products over those of its competitors. The defendant filed a motion to dismiss the relator's amended complaint, asserting that, *inter alia*, providing product support to a customer does not

constitute an illegal kickback. The court has reviewed the parties' submissions and the amended complaint, and will grant the motion to dismiss without prejudice. Because the relator has failed to plead the details of the alleged kickback scheme with sufficient particularity, she has failed to state a claim upon which relief can be granted.

I. PROCEDURAL HISTORY AND FACTUAL BACKGROUND

The relator, Cathleen Forney ("Forney"), has set forth the following allegations in her amended complaint. The defendant, Medtronic, Inc. ("Medtronic"), is a global, publicly-traded medical device company that generates between 8.8 and 9.2 billion dollars per year in the United States. First Am. Compl. ("Am. Compl.") at ¶ 9, Doc. No. 17. Medtronic's Cardio Vascular Group manufactures and distributes devices such as pacemakers, defibrillators, stents, and catheters, and engages in nationwide marketing to promote the purchase of its products. *Id.* at ¶¶ 13, 14. Forney was a district manager for Medtronic's Cardio Vascular Group in the Eastern Pennsylvania District, and worked for the company from 1996 until her termination in 2012. *Id.* at ¶¶ 4, 12. Her employment at Medtronic provided her with direct and independent first-hand knowledge of alleged wrongdoing at the company; namely, Forney alleges that she observed Medtronic providing illegal staffing kickbacks to physicians. *Id.* at ¶ 5.

During the period relevant to this lawsuit, Medtronic marketed a series of products that cardiologists must implant into patients during surgery including, *inter alia*, defibrillators and heart monitoring devices. *Id.* at ¶ 15. Forney alleges that Medtronic engaged in a nationwide marketing scheme for those devices in which Medtronic directed employees to gather extensive data about hospital and physician practices, and to create direct relationships with patients. *Id.* at ¶ 16. Medtronic aimed its marketing at physicians, nurse practitioners, practice administrators, and others who had the ability to impact purchasing decisions. *Id*.

A central part of Medtronic's marketing strategy was to provide free services to its customers. *Id.* While the medical devices at hand were "off-the-shelf commodities," were not new to cardiologists, and had been approved by the United States Food and Drug Administration for at least five years, Medtronic "touted its willingness to provide free services" and positioned itself as a "partner" who added value "through differentiating service and support to all customers." *Id.* at ¶¶ 16, 23. The free services Medtronic provided included free surgical support, implant device follow-up that it continued to offer long after device implantation, and free staff to clinics at which Medtronic employees would spend four to eight hours conducting interrogations and other services. *Id.* at ¶¶ 23, 24. By offering such free services, "Medtronic induced physicians and others with purchasing power to select Medtronic devices" because "the free labor benefitted [the physicians'] bottom line." *Id.* at ¶ 23. Medtronic also used the free services to create direct relationships with patients, and to create patient loyalty and demand for Medtronic products. *Id.* According to a Medtronic job posting, Medtronic sought to employ persons willing to "scrub in" on surgical procedures and to "represent Medtronic during surgeries and implants of products to provide troubleshooting and other technical assistance." *Id.* at ¶ 24.

In the amended complaint, Forney has provided a chart to illustrate the types of free services Medtronic allegedly provided. *Id.* at ¶ 25. For example, on November 9, 2011, the chart indicates that a Medtronic employee performed a "single ICD check" on Patient AJ for Dr. Gulotta. *Id.* At Lehigh Valley Cardiology Associates, a Medtronic employee performed an "interrogation of device" on Patient MB on November 11, 2011, a pacer check on Patient DN on November 22, 2011, a pacer check on Patient RF on December 13, 2011, and a device check on Patient JW on December 29, 2011. *Id.* At St. Luke's Allentown campus, a Medtronic employee

performed an "interrogation of device" on Patient EH on November 16, 2011. *Id.* Forney has also provided a snapshot of the frequency with which Medtronic provided the free services in various Pennsylvania locations, although the pattern allegedly prevailed across the nation. *Id.* In Palmerton, Medtronic provided services for six patients on November 30, 2011, four patients on December 21, 2011, one patient on February 8, 2012, four patients on February 15, 2012, and three patients on February 22, 2012. *Id.* In Quakertown, Medtronic provided services for eleven patients on November 2, 2011, ten patients on January 6, 2012, five patients on February 3, 2012, and four patients on March 2, 2012. *Id.* In Wind Gap, Medtronic provided services for ten patients on December 6, 2011, and ten patients on January 3, 2012. *Id.*

Medtronic's customers billed Medicare, Medicaid, and private insurers for reimbursement for health care provided to patients using Medtronic devices. *Id.* at ¶ 25. Medtronic offered free assistance on billing its devices to federal health care programs, and briefed and updated its customers on how to receive maximum reimbursement from the government. *Id.* at ¶ 17. Medtronic knew that the Centers for Medicare & Medicaid Services ("CMS") requires that its customers submit a form for reimbursement requiring providers to certify that they have not violated the federal anti-kickback statute. *Id.* at ¶¶ 18, 20, 21. Thus, Medtronic caused providers to submit false claims for payment to fiscal intermediaries because physicians and hospitals received staffing kickbacks from Medtronic, submitted claims for payment, and falsely certified that they had complied with the anti-kickback laws and regulations. *Id.* at ¶ 25.

Finally, Forney alleges that Medtronic documented its nationwide and continuous payment of alleged staffing kickbacks in Google Calendar and SalesForce software, which Medtronic used to track scheduled cases across the nation. *Id.* at ¶ 26. Forney alleges that using

an unsecured internet program such as Google Calendar to transmit health information amongst sales representatives and clinical specialists violated the Health Insurance Portability and Accountability Act ("HIPAA"). *Id.* Further, Medtronic knew that it was violating HIPAA by disseminating patient data over unsecured programs, as evidenced by the 10-K Form it submitted to the United States Securities and Exchange Commission in 2013 in which Medtronic stated that "[s]ome modifications to our systems and policies may be necessary" to meet the expectation of the HIPAA rules. *Id.* at ¶ 27.

Forney filed a complaint against Medtronic under seal on November 20, 2015, alleging violations of the FCA and twenty-nine state false claims statutes. Doc. No. 1. The United States government requested that the seal be extended multiple times before it, along with the plaintiff states, declined to intervene on December 12, 2016. *See* Doc. Nos. 3, 7, 9, 10. The court unsealed the complaint on December 14, 2016, and Forney served the complaint on Medtronic on March 15, 2017. Doc. Nos. 11, 15. Forney filed a first amended complaint on April 3, 2017. Doc. No. 17. The parties stipulated to an extension of time for Medtronic's response to the amended complaint, and Medtronic filed the present motion to dismiss on April 24, 2017. Doc. Nos. 18, 30. Forney filed a response in opposition to the motion on May 15, 2017, and Medtronic filed a reply in further support of its motion on May 30, 2017. Doc. Nos. 31, 34. The court heard oral argument on the motion from counsel for the parties on June 1, 2017.

II. DISCUSSION

A. Standard of Review

Federal Rule of Civil Procedure 12(b)(6) allows a party to move for dismissal of a complaint or a portion of a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A motion to dismiss under Rule 12(b)(6) tests "the sufficiency

of the allegations contained in the complaint." *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993) (citation omitted). As the moving party, "[t]he defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005) (citation omitted).

In general, a complaint is legally sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "The touchstone of [this] pleading standard is plausibility." *Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012). Although Rule 8(a)(2) does "not require heightened fact pleading of specifics," it does require the recitation of "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). In other words, "[t]he plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quotation omitted). Ultimately, a complaint must contain facts sufficient to nudge any claim "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570.

In implementing the overarching plausibility standard, the court is required to conduct a three-part inquiry. First, the court must "outline the elements a plaintiff must plead to a state a claim for relief." *Bistrian*, 696 F.3d at 365 (citations omitted). Second, the court must identify allegations that are not "entitled to the assumption of truth" because they "are no more than conclusions." *Id.* (citations omitted). Thus, legal conclusions, whether in pure form or "couched as factual allegation[s]," and conclusory factual allegations are not entitled to be assumed true. *See Iqbal*, 556 U.S. at 678, 681 (quoting *Twombly*, 550 U.S. at 555); *Siwulec v.*

J.M. Adjustment Servs., LLC, 465 F. App'x 200, 202 (3d Cir. 2012). Finally, the court must "look for well-pled factual allegations, assume their veracity, and then 'determine whether they plausibly give rise to an entitlement to relief.'" *Bistrian*, 696 F.3d at 365 (quotations omitted). This determination is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679 (citation omitted).

Additionally, claims brought pursuant to the FCA must be plead with particularity in accordance with Rule 9(b) of the Federal Rules of Civil Procedure. *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 n.9 (3d Cir. 2004) (citing *U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998)). Rule 9(b) rqeuires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Thus, in cases in which the heightened pleading standard of Rule 9(b) applies, plaintiffs must "plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984). Further, a complaint must provide "all of the essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir. 1997)).

B. Analysis

Forney presents a novel theory of FCA liability in this case. She alleges that Medtronic paid healthcare providers kickbacks by providing them with free product support services, which

induced the providers to choose Medtronic devices over competing devices. Because such kickbacks allegedly violated the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and because CMS required providers to whom Medtronic paid such kickbacks to certify compliance with the AKS, Medtronic caused the providers to submit false claims. Thus, Forney contends that Medtronic is subject to liability under the FCA.

1. FCA Claim

Forney's FCA claim rests on Medtronic's alleged violations of the Anti-Kickback Statute ("AKS").[1] Under the AKS, it is unlawful to knowingly and willfully solicit or receive "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" for referrals of services covered by federally funded medical services, such as Medicare and Medicaid. 42 U.S.C. § 1320a-7b(b). Thus, for the conduct at hand to amount to paying kickbacks in violation of the AKS, Forney must allege that Medtronic (1) knowingly and willfully (2) solicited or received remuneration (3) in return for, or to induce, referrals to a person or entity for services covered by a federally funded healthcare program. *See U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014).

The court recognizes that medical device manufacturers and distributors like Medtronic may be subject to FCA liability for knowingly paying kickbacks to a provider knowing that the provider will seek reimbursement from CMS, and that CMS will require a compliance certification. *See Schmidt*, 386 F.3d at 224. The court also recognizes that Forney has sufficiently alleged that Medtronic's free services induced physicians to choose Medtronic products, thus sufficiently alleging the third requirement of a prima facie case: that one purpose

[1] Forney also mentions violations of the Stark Law, 42 U.S.C. § 1395nn, and HIPAA. She has not pleaded any facts related to the Stark Law, nor does the amended complaint mention the Stark Law in Count I. Thus, the court assumes that the basis of the FCA claim in Count I is the AKS, and will not address the Stark Law. As to HIPAA, there is no legal claim based on the HIPAA violations in the amended complaint; thus, it is unnecessary to discuss whether Medtronic violated HIPAA or whether such a violation may form the basis of a FCA *qui tam* action.

of the free services was to induce future purchases. *See United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (holding that an AKS violation occurs even where only one purpose of the remuneration is to induce providers to use the defendant's products or services in the future). The FCA claim in Count I of the amended complaint, however, is deficient in several crucial respects.

First, Forney has failed to allege with particularity how the free services Medtronic provided to physicians constituted illegal remuneration under the AKS. Guidance from the Office of Inspector General suggests that product support services that are "specifically tied to support of the purchased product" standing alone do not implicate the AKS, but that such services may constitute illegal remuneration if those services provide some "substantial independent value to the purchaser." Office of Inspector General, U.S. Department of Health and Human Services, Compliance Program Guide for Pharmaceutical Manufacturers at 19-20 (2003).[2] Thus, according to administrative guidance, such product support services are permissible unless they are not tied to the product purchased, or if they provide some substantial independent value to the purchaser. While the amended complaint alleges that the free services "benefitted physician practices" and that the "free labor benefited [the physicians'] bottom line," *see* Am. Compl. at ¶ 23, Forney has failed to allege with the particularity Rule 9(b) requires that the free services saved the providers money. For example, Forney has not specified which of the services that Medtronic provided in exchange for purchasing Medtronic products would have had to have been otherwise performed by the physician or the physician's staff. All that Forney has alleged with particularity about the free services themselves is that Medtronic provided technical product support in connection with the purchase of its products. Offering well-supported

[2] The court recognizes that such administrative guidance does not constitute binding law, but finds it persuasive in deciding whether the conduct alleged falls under the AKS's umbrella of illegal remuneration.

products might induce physicians to purchase Medtronic products, but only because they are better-supported products than competing products. If Forney files a second amended complaint, she must describe with sufficient specificity how Medtronic's free services crossed the line separating permissible product support from illegal remuneration with independent value to the purchaser. She must also demonstrate that any independent value to the purchaser was *substantial*. Simply stating that the services generally benefited Medtronic's customers' bottom lines or that physicians used Medtronic's services "in lieu of having to pay for their own employees," *see* Am. Compl. at ¶ 1, is not sufficiently specific to meet the pleading requirements of Rule 9(b) without alleging *how* those services substantially benefited customers' bottom lines.

Second, Forney has failed to allege that Medtronic acted "knowingly and willfully" as required by the AKS. *See* 42 U.S.C. § 1320a-7b(b). Knowledge in this context means actual knowledge that the alleged false claims were fraudulent, deliberate ignorance as to the claims' fraudulent nature, or reckless disregard of the claims' truth or falsity. *Schmidt*, 386 F.3d at 241 (citing 31 U.S.C. § 3729(b)). Forney alleges in the amended complaint that "Medtronic touted its willingness to provide free services," Am. Compl. at ¶ 16, Medtronic was familiar with CMS's billing processes and certification requirements, *id.* at ¶ 17-18, and that "Medtronic induced physicians and others with purchasing power to select Medtronic devices." *Id.* at ¶ 23. Forney has not, however, alleged that any Medtronic employee knew that providing free services violated the AKS or that the providers Medtronic serviced would submit false claims. Further, while Forney alleges that the effect of the scheme was to induce physicians to refer Medtronic's products to their patients, Forney has not alleged that its subjective purpose was to do so.

Finally, Forney has failed to connect the alleged kickbacks to resulting false claims with sufficient particularity. While a relator need not "identify a specific claim for payment at the

pleading stage of the case to state a claim for relief," *U.S. ex rel. Wilkins v. United Health Group, Inc*., 659 F.3d 295, 308 (3d Cir. 2011), a relator must allege "reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014). In the amended complaint, Forney generally alleges that Medtronic's customers billed "Medicare, Medicaid, and private insurers" and provides a sample list of providers to whom Medtronic provided free services and "caused to submit false claims for reimbursement." Am. Compl. at ¶ 25. These conclusory allegations that the providers to whom Medtronic provided free services generally submitted claims to the government do not suffice, and the mere fact that Medtronic did, in fact, provide free services to particular doctors on particular dates does not amount to reliable indicia leading to a strong inference that the providers subsequently submitted claims to Medicare or Medicaid.

For the foregoing reasons, the court will dismiss Count I of the amended complaint alleging a violation of the FCA. The court, however, will dismiss the claim without prejudice and will provide Forney with the opportunity to replead that claim.

2. State Law Claims

Because Forney alleges that Medtronic's staffing kickbacks occurred on a nationwide scale, and that Medtronic engaged in a nationwide marketing scheme to promote those kickbacks, she has brought claims under twenty-nine analog state false claims statutes in addition to her claim under the FCA. Notably, she has not brought any claims under Pennsylvania law because Pennsylvania has not enacted any false claims legislation.

The amended complaint states that Medtronic's alleged kickback scheme was "nationwide," Am. Compl. at ¶¶ 14, 24, 26, and that Medtronic engaged in "nationwide marketing." *Id*. at ¶ 14. It does not, however, reference any actual claims, services, providers, or

conduct located outside of Pennsylvania. At least one court in this district has held that such blanket allegations of a nationwide scheme do not meet the particularity requirement of Rule 9(b) and cannot support claims under other states' statutes. *Hericks v. Lincare Inc.*, No. CIV. A. 07-387, 2014 WL 1225660, at *8 (E.D. Pa. Mar. 25, 2014). In cases in which relators have alleged enough to sustain claims under state false claims statutes, the complaints have contained more facts that could raise the inference that the defendants' conduct occurred nationwide. In *United States v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 496 (E.D. Pa. 2016), for example, the court held that the relator sufficiently alleged a nationwide scheme because although the relator did not plead specific facts in every state, he alleged that dozens of specific hospitals around the country were the defendant's clients and that the defendant provided specific services for over half of country's hospitals. *See also U.S. ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 177 (E.D. Pa. 2012). Forney's mere allegation in the amended complaint that Medtronic engaged in "nationwide marketing" is not enough to survive dismissal of her state law claims. The amended complaint does not specify any customers of Medtronic outside the state of Pennsylvania, nor do the factual allegations contained in the amended complaint mention the names of any states aside from Pennsylvania—Forney only mentions other states when she states causes of action under the laws of those states. Thus, the court will also dismiss Forney's state law claims in the amended complaint without prejudice, and will allow her to replead those claims as well.

III. CONCLUSION

After examining the allegations in the amended complaint, the parties' submissions, and the parties' arguments before the court, the court finds that the relator has failed to set forth sufficient allegations establishing a cognizable claim against the defendant. Accordingly, the

court will dismiss the amended complaint in its entirety, but will do so without prejudice so as to allow the relator an opportunity to amend. The relator may file a second amended complaint within 14 days of the date of the memorandum opinion and accompanying order.

A separate order follows.

BY THE COURT:

/s/ *Edward G. Smith*
EDWARD G. SMITH, J.